IN THE UNITED STATES PATENT AND TRADEMARK OFFICE
BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

In re Application of:	**LaFont et al.**
Application No.:	**10/785,349**
Filed:	**February 24, 2004**
For:	**High Temperature Stent Delivery System**
Examiner:	**Ann Schillinger**
Group Art Unit:	**3738**

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Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Docket No.: S63.2-9776-US02

AMENDED APPEAL BRIEF

This is an Amended Appeal Brief for the above-identified application in which claims 1-2 and 4-8 were finally rejected in a Final Office Action mailed November 16, 2006. Currently, claims 1-2 and 4-8 are pending in the application.

A Notice of Appeal was filed in this case on February 16, 2007. The fees required under §1.17(c) for filing this brief were addressed in the Notice of Appeal. The Commissioner is authorized to charge Deposit Account No. 22-0350 for any other fees which may be due with this Appeal.

A copy of the claims on appeal is presented in the **Claims Appendix** below.

(B) Table of Contents

(C) Real Party in Interest

The Application is assigned to Boston Scientific Scimed, Inc., formerly known as Scimed Life Systems, Inc., One SciMed Place, Maple Grove, Minnesota 55311-1566, a Minnesota corporation and a subsidiary of Boston Scientific Corporation, One Boston Scientific Place, Natick, Massachusetts 01760-1537, a Delaware Corporation.

(D) Related Appeals and Interferences

At present there are no related appeals or interferences.

(E) Status of Claims

Claims 1-2 and 4-8 were finally rejected and appealed. Claim 3 was cancelled.

In the Final Office Action, claim 1 was rejected under 35 USC 102(e) as being anticipated by Mikus et al (US. Appln. No. 2002/0035391); claims 2, 6 and 7 were rejected under 35 USC 103(a) as being unpatentable over Mikus et al in view of Boylan et al (US Appln. No. 2003/0187497); claims 4 and 5 were rejected under 35 USC 103(a) as being unpatentable over Mikus et al in view of Guglielmi et al (6,011,995); and claim 8 was rejected under 35 USC 103(a) as being unpatentable over Mikus et al in view of Boylan et al and further in view of Guglielmi et al.

(F) Status of Amendments

Subsequent to the Final Office Action of November 16, 2006, Applicant filed a Response After Final and Request for Reconsideration on January 16, 2007. In the Advisory Action of February 12, 2007, the Examiner indicated that the Request for Reconsideration had been considered but did not place the application in condition for allowance.

(G) Summary of Claimed Subject Matter

A summary of representative claims and a non-limiting listing of locations where support may be found [bracketed citations] is provided as follows:

Independent claim 1 recites a method of treating a bodily vessel comprising the steps of inserting a catheter having a distal portion into a body vessel (page 2, lines 31-32), the distal portion having an expandable region (page 5, lines 2-3), an expandable stent being disposed about at least a portion of the expandable region (page 5, lines 3-4); advancing the distal portion to a desired location in a bodily vessel (page 6, 23-24); delivering the stent to the desired location by expanding the expandable region from an unexpanded diameter to an expanded diameter (page 6, lines 27-29); and delivering heat to the stent during the expansion of the expandable region (page 5, line 21- page 6 line 11; page 6, lines 24-26).

Independent claim 6 recites a method of treating a bodily vessel comprising the steps of advancing a stent delivery catheter comprising a stent constructed substantially of stainless steel disposed about at least a portion of an expandable region to a desired location in a bodily vessel (page 5, lines 2-4; page 5, line 10; page 6, 23-24); delivering the stent in the bodily vessel at the desired location (page 6, lines 23-24); and heating the stent during delivery (page 5, line 21- page 6 line 11; page 6, lines 24-26).

(H) Grounds of Rejection to be Reviewed on Appeal

1. Whether the Examiner erred in rejecting claim 1 under 35 U.S.C. §102(e) as being unpatentable over U.S. Application No. 2002/0035391 to Mikus et al.

2. Whether the Examiner erred in rejecting claims 2, 6-7 under 35 USC 103(a) as being unpatentable over U.S. Application No. 2002/0035391 to Mikus et al. in view of U.S. Application No. 2003/0187497 to Boylan et al.

3. Whether the Examiner erred in rejecting claims 4 and 5 under 35 USC 103(a) as being unpatentable over U.S. Application No. 2002/0035391 to Mikus et al. in view of U.S. Patent 6,011,995 to Guglielmi et al.

4. Whether the Examiner erred in rejecting claim 8 under 35 USC 103(a) as being unpatentable over U.S. Application No. 2002/0035391 to Mikus et al. in view of U.S. Application No. 2003/0187497 to Boylan et al. and in further view of U.S. Patent 6,011,995 to Guglielmi et al.

(I) Argument

1. The Examiner erred in rejecting claim 1 under 35 U.S.C. §102(e) as being unpatentable over U.S. Application No. 2002/0035391 to Mikus et al.

In the Final Office Action, claim 1 was rejected under 35 U.S.C. §102(e) as being unpatentable over U.S. Application No. 2002/0035391 to Mikus et al. Instant claim 1 recites "an expandable stent being ***disposed about*** at least a portion of the expandable region" (emphasis added). In the Final Office Action, Examiner reasserts that the broadest meaning of the term "about" in the Merriam-Webster Dictionary is "reasonably close to" or "in the vicinity."

The MPEP provides guidance on the issue of interpreting claims during prosecution. MPEP 2111 states that:

> During patent examination, the pending claims must be "given their ***broadest reasonable interpretation consistent with the specification***." (emphasis added)
>
> The broadest reasonable interpretation of the claims must also be consistent with the interpretation that those skilled in the art would reach.

MPEP 2111.01 III explains further that:

> "[T]he ordinary and customary meaning of a claim term is the meaning that the term would have to a person of ordinary skill in the art in question at the time of the invention, *i.e.*, as of the effective filing date of the patent application." citing *Phillips v. AWH Corp.*, *>415 F.3d 1303, 1313<, 75 USPQ2d 1321>, 1326< (Fed. Cir. 2005) (*en banc*).
>
> It is the use of the words in the context of the written description and customarily by those skilled in the relevant art that accurately reflects both the "ordinary" and the "customary" meaning of the terms in the claims.
>
> ***If extrinsic reference sources***, such as dictionaries, ***evidence more than one definition for the term, the intrinsic record***

> ***must be consulted*** to identify which of the different possible definitions is most consistent with applicant's use of the terms. (emphasis added)

In addition, the Federal Circuit, in the recent case of *Phillips v. AWH Corp.*, 75 U.S.P.Q.2d 1321, 1326 (Fed. Cir. 2005) states that:

> "a person of ordinary skill in the art is deemed to ***read the claim term*** not only in the context of the particular claim in which the disputed term appears, but ***in the context of the entire patent, including the specification***" (emphasis added).

In the present application, the context and use of the term "disposed about" in the claims and specification make the meaning of the phrase both clear and understandable. Instant claim 1 recites that an expandable stent is disposed about at least a portion of the expandable region. As used here, the word "about" clearly modifies the word "disposed" to illustrate that the stent is positioned and surrounds at least a portion of the expandable region. Nothing in the claim language would indicate to one of ordinary skill any other meaning of the phrase. Certainly, there is nothing to indicate that the stent is merely near or "relatively close to" the expandable region. Such an interpretation of the phrase "disposed about" would simply ignore the clear meaning of the phrase as well as its context of use.

Though Applicant believes the meaning of "disposed about" is apparent from the usage and context in the claims themselves, the specification and figures of the instant application provide the context in which the meaning of "disposed about" can be determined. For example, in reference to Fig. 1, the specification states that "[c]atheter 100 includes an inner member 104 ***about which stent 114 is disposed***" (page 4, lines 18-19). Other references to one portion of the catheter assembly being "disposed about" another portion of the catheter assembly are: the "[o]uter member 106 is ***disposed about*** inner member 104" and, if a balloon expandable

stent is used, the "balloon 108 is ***disposed about*** inner member 104" with the "[s]tent 114 … ***disposed about*** balloon 108" (page 4, lines 21-22 and page 5, lines 2-4, for other examples of the use of the term "disposed about" see page 5, line 13 and lines 30-32 and page 6, lines 1-2).

Furthermore, the meaning of "disposed about" is illustrated in annotated Fig. 4 of the instant application, provided below.

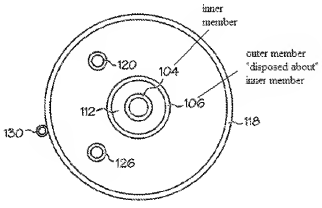


FIG. 4

As shown above, Fig. 4 is a cross-section of the catheter and shows that the "[o]uter member 106 is ***disposed about*** inner member 104" (page 4, lines 21-22). Rather than referring to elements being near or "reasonably close to," as used in the present application, in every instance, the term "disposed about" refers to the relative position of one tubular element surrounding some portion of another element … in other words an element is "disposed about" the other. The present application provides for no other interpretation of this phrase.

When an extrinsic source such as a dictionary is consulted, it is clear that the definition of "about" in the term "disposed about" which is most consistent with applicant's use

of the term in this application is "on all sides" or "around," ***not*** "reasonably close to" or "in the vicinity," as asserted by Examiner.

With this definition of "disposed about" in mind, it is clear that Mikus does not teach or suggest all the elements of instant independent claim 1. The expandable region in Mikus is a mesh basket (14) that is expanded by pushing the catheter outer shaft distally over the catheter inner shaft (see [0032]). As shown in annotated Figs. 5 and 7 provided below, the stent (7) is positioned a distance away from the mesh basket (14).

FIG. 5

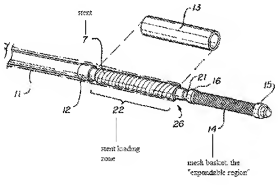
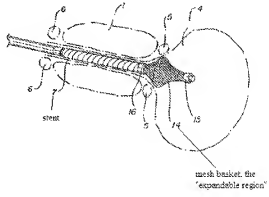


FIG. 7



In reference to the relative positions of the stent (7) and the mesh basket (14), Mikus states that "[t]he stent is best placed … downstream of the bladder neck sphincter" so "the distance between the anchor and stent [is] chosen and controlled during manufacture to approximate the desired distance between the bottom of the bladder and the desired release point for the stent at a location downstream of the bladder neck sphincter" (see [0029]).

Mikus further states that "[t]he proximal face of the now toroidal mesh basket [i.e. after the mesh basket has been expanded] is seated against the bladder neck sphincter and the

distance between the stent and the mesh basket is large enough to ensure that the stent is not within the lumen of the bladder neck sphincter, so that it can not interfere with normal operation of the bladder neck sphincter" (see [0034]).

Based on the figures and specification of Mikus, Applicants assert that a cross-sectional view of either Figs. 5 or 7, similar to that of Fig. 4 of the instant application, does not show "an expandable stent being ***disposed about*** at least a portion of the expandable region," as recited in claim 1.

The Final Office Action also asserts that paragraph [0025] of Mikus discloses "delivering a stent to a certain location via the use of the stent's expandable region (Final Office Action, page 5). Mikus however, fails to teach or suggest "delivering the stent to the desired location by expanding the expandable region from an unexpanded diameter to an expanded diameter," as recited in instant claim 1. The expandable region of the Mikus delivery system is the mesh basket 14. As discussed previously and shown in Figs. 2-7 of Mikus, the stent in Mikus is not disposed about the mesh basket 14 but is placed a distance away from the mesh basket 14 so that expansion of the mesh basket does not expand the stent.

For at least these reasons, Mikus does not teach or suggest all the elements of instant independent claim 1. Applicants request reversal of the rejection and assert that claim 1 is in condition for allowance.

2. The Examiner erred in rejecting claims 2, 6-7 under 35 USC 103(a) as being unpatentable over U.S. Application No. 2002/0035391 to Mikus et al. in view of U.S. Application No. 2003/0187497 to Boylan et al.

In the Final Office Action claims 2, 6-7 were rejected under 35 USC 103(a) as being unpatentable over U.S. Application No. 2002/0035391 to Mikus et al. in view of U.S. Application No. 2003/0187497 to Boylan et al. Claim 6 is an independent claim and claims 2 and 7 are dependent claims.

As discussed above, Mikus does not teach or suggest all of the elements of instant independent claims 1 or 6, namely, "a stent … disposed about at least a portion of an expandable region." The proposed addition of the stent of Boylan at least partially constructed of stainless steel does nothing to address the failure of Mikus to teach or suggest all of the elements of instant claims 2, 6 and 7. Applicant request reversal of the rejection and assert that claims 2, 6 and 7 are in condition for allowance.

3. The Examiner erred in rejecting claims 4 and 5 under 35 USC 103(a) as being unpatentable over U.S. Application No. 2002/0035391 to Mikus et al. in view of U.S. Patent 6,011,995 to Guglielmi et al.

In the Final Office Action, claims 4 and 5 were rejected under 35 USC 103(a) as being unpatentable over U.S. Application No. 2002/0035391 to Mikus et al. in view of U.S. Patent 6,011,995 to Guglielmi et al. Claims 4 and 5 are dependent upon instant independent claim 1. As discussed above, Mikus does not teach or suggest all of the elements of instant independent claim 1. The proposed addition of the heated contrasting agent of Guglielmi to

Mikus does nothing to address the failure of Mikus to teach or suggest all of the elements of instant dependent claims 4 and 5. Applicants request reversal of the rejection and assert that dependent claims 4 and 5 are in condition for allowance.

4. The Examiner erred in rejecting claim 8 under 35 USC 103(a) as being unpatentable over U.S. Application No. 2002/0035391 to Mikus et al. in view of U.S. Application No. 2003/0187497 to Boylan et al. and in further view of U.S. Patent 6,011,995 to Guglielmi et al.

In the Final Office Action, claim 8 was rejected under 35 USC 103(a) as being unpatentable over U.S. Application No. 2002/0035391 to Mikus et al. in view of U.S. Application No. 2003/0187497 to Boylan et al. and in further view of U.S. Patent 6,011,995 to Guglielmi et al. Claim 8 is dependent upon independent claim 6. The proposed addition of the stent of Boylan at least partially constructed of stainless steel and the heated contrasting agent of Guglielmi does nothing to address the failure of Mikus to teach or suggest all the elements of independent claim 6. Applicants request reversal of the rejection and assert that dependent claim 8 is in condition for allowance.

CONCLUSION

Instant claims 1-2 and 4-8 are patentably distinct over Mikus; over Mikus in view of Boylan; over Mikus in view of Guglielmi; and over Mikus in view of Boylan and further in view of Guglielmi. Consequently reversal of the rejection and objection is respectfully requested.

Respectfully submitted,

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Date: June 25, 2007

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(J) Claims Appendix

Claim 1. A method of treating a bodily vessel comprising the steps of:

inserting a catheter having a distal portion into a body vessel, the distal portion having an expandable region, an expandable stent being disposed about at least a portion of the expandable region;

advancing the distal portion to a desired location in a bodily vessel;

delivering the stent to the desired location by expanding the expandable region from an unexpanded diameter to an expanded diameter;

delivering heat to the stent during the expansion of the expandable region.

Claim 2. The method of claim 1 wherein the stent is at least partially constructed of stainless steel.

Claim 4. The method of claim 1 wherein the expanded region is expanded by delivering a heated contrast agent to the expandable region.

Claim 5. The method of claim 1 wherein a heated contrast agent is delivered to the distal portion as the stent is delivered.

Claim 6. A method of treating a bodily vessel comprising the steps of:

advancing a stent delivery catheter comprising a stent constructed substantially of stainless steel disposed about at least a portion of an expandable region to a desired location in a bodily vessel; delivering the stent in the bodily vessel at the desired location; and heating the stent during delivery.

Claim 7. The method of claim 6 wherein the stent is conductively heated by directing energy to the stent through a portion of the catheter.

Claim 8. The method of claim 7 wherein the bodily vessel is heated by the stent.

(K) Evidence Appendix - None

(L) Related Proceedings Appendix - None